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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,287	10/01/2003	Richard Hochberg	Y03-076US	7077

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1628	

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09/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,287	HOCHBERG, RICHARD	
	Examiner	Art Unit	
	Barbara P. Badio	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 39-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 39-75 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 39-75 are pending in the present application. The instant claims stand rejected as indicated below.

Claim Rejections - 35 USC § 112

3. The rejection of claims 57-64 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant argues the claimed "compounds are SERMs and like traditional SERMs such as tamoxifen and raloxifene, have similar activity to, but completely different chemistry from tamoxifen and raloxifene, which are recognized in the art for use in inhibiting the recurrence of breast cancer". According to applicant, pursuant to MPEP 2163.02, an objective standard for the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed" and, thus, it is applicant's position that the present application, clearly provides sufficient description of the claimed invention. Applicant's argument was considered but not persuasive for the following reasons.

According to MPEP § 2163, to satisfy the written description requirement, the present specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Even if one of skilled in the art at the time of the present invention agrees that tamoxifen and raloxifene, known SERMs, are effective in inhibiting the recurrence of breast cancer as suggested by applicant, he can not make the same assumption for the claimed compounds. As noted by applicant, the claimed compounds have different chemistry from tamoxifen and raloxifene and, thus, the skilled artisan would have the reasonable expectation of differences in the activity.

As noted by applicant, the objective standard for the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." not an indication of a result that one might hope to achieve if the claimed compounds are administered. The present specification lacks adequate written description of the patient population and how one would determine said reduction in the likelihood of a recurrence of breast cancer.

For the reasons given above and those given in the previous Office Action, the rejection of claims 57-64 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

4. The rejection of claims 48-51 and 65-73 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

5. The rejection of claims 39-47, 52-56 and 65-73 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 103

6. The rejection of claims 39-56 and 65-73 under 35 USC 103(a) over Van den Broek et al. (US 3,972,906) is maintained and claims 57-64, 74 and 75 are rejected under 35 USC 103(a) over Van den Broek et al. (US 3,972,906).

Applicant argues the instant invention represents the first use of SERM's to treat menopausal symptoms while reducing the risk that the patient develops, or experiences a recurrence of an estrogen-sensitive cancer, to treat an estrogen-sensitive cancer or to reduce the likelihood of a recurrence of breast cancer in a patient. Applicant also argues the reference does not (a) teach or suggest that any of the prior art compounds exhibit selective estrogen receptor modulator activity, (b) exemplified any biological activity of any of the prior art compounds and (c) exemplified compounds having 17α-substituent of greater than 3 non-hydrogen atoms in length as recited by the instant claims. Lastly, it is applicant's argument that the estrogen agonists are contraindicated in patients with or at risk for estrogen-sensitive cancer and the present specification (Table 1 and 2) shows the short-chain compounds disclosed by the reference do indeed exhibit estrogenic activity. Applicant's argument was considered but not persuasive for the following reasons.

First, the fact that the reference does not teach the SERM activity of the prior art compound is irrelevant since a compound and its properties are inseparable.

Secondly, the prior art does not have to specifically treat that which would be obvious to the skilled artisan in the art at the time of the invention. In other words, the prior art teaches the use of estrogen agonists in the treatment of estrogen-deficiency syndromes such as menopausal symptoms and breast cancer. Thus, it would have been obvious to the skilled artisan in the art at the time of the cited prior art to utilize the compounds of van den Broek which are estrogen agonists in the treatment of estrogen-deficiency syndromes including those encompassed by the claimed invention based on the knowledge in the art as to the utilization of estrogen agonists.

Third, applicant argues unexpected activity and reference is made to Tables 1 and 2 of the present specification. However, as evidenced by Table 1, compounds with 5 non-hydrogen atoms in length may also be agonist, see E11-2,2Rev. Thus, contrary to applicant's argument of unexpected results, the data in the present specification provides evidence that the property of the compounds is dependent on the specific chain and not just the chain length. The data in the present specification does not commensurate in scope of the present claims.

Fourth, as noted by the present specification, the claimed compounds are not pure antagonists and there is no evidence of record that the biological property ,i.e., effect on estrogen-deficiency syndromes, as taught by the reference differs. Based on the teachings of van den Broek, including the definition of lower alkoxy or acyloxy, the skilled artisan would have the reasonable expectation that the modification of the exemplified prior art compound by replacing the 11β-methoxymethyl group with a 11β-cyclopentyloxy, cyclohexenyloxy, butyryloxy, etc. (see page 2, lines 24-28) would result

in compounds having similar biological properties as taught by the cited prior art and, thus, use as encompassed by the instant claims.

In summary, as noted by MPEP § 2112, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco, Inc.* 190 F.3d 1342, 1347, 51 USPQ 2d 1943, 1947 (Fed. Cir.) 1999). Thus, while known compositions may be claimed in new methods of treating conditions for which they were previously unknown to have therapeutic value, the claiming of a new *property* which was inherently present in the prior art composition at all times does not distinguish it over the prior art. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430,433 (CCPA 1977). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.")
See also MPEP §2112.

In regards to amended claim 57, it is noted that treatment of breast cancer would inherently result in the reduction of the likelihood of a recurrence of breast cancer in said patient and, thus, claims 57-64 are made obvious by the cited reference.

For these reasons and those given in the previous Office Actions, the rejection of claims 39-56 and 65-73 under 35 USC 103(a) over Van den Broek et al. (US 3,972,906) is maintained and claims 74 and 75 are rejected under 35 USC 103(a) over Van den Broek et al. (US 3,972,906).

7. The rejection of claims 39-56 and 65-73 under 35 USC 103(a) over Broek et al. (US 3,972,906) in view of Cameron et al. (US 2001/0025051), Palkowitz (US6,268,361) and Bodor et al. (US 4,617,298) is maintained and claims 74 and 75 are rejection under 35 USC 103(a) over Broek et al. (US 3,972,906) in view of Cameron et al. (US 2001/0025051), Palkowitz (US6,268,361) and Bodor et al. (US 4,617,298).

Applicant's arguments in regards to Broek are discussed above in #6.

In regards to the argument to Cameron, Palkowitz and Bodor and applicant's argument that the compounds therein are not related to the present invention, the examiner notes as stated in the previous Office Action, the references were utilized for their teachings of the utilization of estrogens in the treatment of menopausal symptoms, osteoporosis as well as estrogen-dependent cancer such as breast cancer.

For these reasons and those given in the previous Office Actions, the rejection of claims 39-56 and 65-73 under 35 USC 103(a) over Broek et al. (US 3,972,906) in view of Cameron et al. (US 2001/0025051), Palkowitz (US6,268,361) and Bodor et al. (US 4,617,298) is maintained and claims 74 and 75 are rejection under 35 USC 103(a) over

Broek et al. (US 3,972,906) in view of Cameron et al. (US 2001/0025051), Palkowitz (US6,268,361) and Bodor et al. (US 4,617,298).

Response to Dr. Hochberg's declaration

8. The declaration argues the compounds as set forth in the claims exhibit unexpected activity as SERM and the cited reference does not exemplify any biological activity associated with the prior art compounds or any of the compounds used in the present invention.

As noted above in #6, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." The utilization of the claimed compounds as recited by the instant claims is made obvious by the teachings of the cited prior art and the level of skilled of the ordinary artisan in the art at the time of the present invention. The discussion presented above in #6 is incorporated herein.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetter can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/

Primary Examiner, Art Unit 1628